IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

RAMONIA LONGS, individually and as Executor of the Estate of Mary Buchanan, deceased; PHYLLIS J. HESTER; GLENORA ANDERSON; and OLIVER WIMBUSH, Plaintiffs, v. WYETH, formerly known as AMERICAN HOME PRODUCTS CORPORATION; et. al), Defendants.	C.A. No. 1: 03 CV 2042 JUDGE: Solomon Oliver, Jr. Personal Injury Action (28 U.S.C. §1332) DEMAND FOR JURY TRIAL Related to MDL No. 1203 (C.A. No. 2:04 - 20223) (In Re: Diet Drugs) "PPH" Case

PLAINTIFFS' RESPONSE TO WYETH'S MOTION FOR PARTIAL SUMMARY JUDGMENT RELATING TO PUNITIVE DAMAGES

Wyeth's motion argues that plaintiffs are barred from seeking punitive damages because under Ohio law plaintiffs must prove Wyeth withheld information from or misrepresented information to the Food and Drug Administration (FDA), and that this aspect of Ohio punitive damages law is contrary to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Wyeth's argument fails for two reasons:

(1) Plaintiffs' request for punitive damages is not a claim or cause of action based on fraud-on-the-FDA, which would be barred by *Buckman*, and plaintiff makes no such fraud-on-the-FDA claims. The underlying causes of action (design defect and negligence) are not grounded in fraud. Plaintiffs simply seek punitive damages resulting from injuries related to their product liability and negligence claims, but there is no separate cause of action for punitive damages. The question is whether evidence of fraud on the FDA is admissible when relevant not to proving a cause of action, but to satisfy a state imposed element of recovery of punitive damages.

(2) If the court finds that Ohio statute § 2307.80(C) (that the plaintiff can avoid the punitive damages ban by providing evidence of what the manufacturer provided or failed to provide to the FDA) is unconstitutional pursuant to *Buckman*, then the court should find that this provision of the act is severable. Severing section (C) from the act leaves in place plaintiffs' right to seek punitive damages in a products liability case and removes the ban on punitive damages related to FDA-approved drugs.

SUMMARY OF THE CASE

Decedent, Mary Buchanan, lived in Cleveland, Ohio. She died in December 2003 at the age of 66 years. When she became ill, decedent was treated at the Cleveland Clinic Hospital. The Cleveland Clinic pulmonologist, Robert Schilz, M.D., diagnosed decedent with PPH associated with her use of diet pills. Also, Dr. Schilz, a PPH expert now at University Hospitals, is one of the expert witnesses for plaintiffs in this case.

Decedent used Redux for some time between 1996 and 1997, the exact amount of time is not certain. Although decedent died without children or surviving spouse, she was very close to her brother, sisters, nieces and nephews.

OVERVIEW OF FEN-PHEN, REDUX, AND WYETH'S CONDUCT

"Fen-phen" refers to the use of fenfluramine in combination with phentermine.[1] Wyeth was the sole supplier of fenfluramine in the United States, and Wyeth's trade name for fenfluramine was Pondimin. Fenfluramine (Pondimin) is 50% dexfenfluramine, which is the active ingredient of Pondimin.[2]

Wyeth knew fenfluramine and dexfenfluramine caused PPH as early as 1993,[3] with further notice in March 1995,[4] but Wyeth took no steps to inform physicians about these

[1] Ex. E006, Deitch deposition (Texas), 3/5/98 at 181.

[2] Ex. E006, Deitch deposition (Texas) at 175-176.

[3] Ex. E015, Rich MDL deposition at 246-248, 310-312, 319-321; Ex. E005, Davis MDL deposition at 71-72; Ex. E007, DeVane MDL deposition at 164-165; Ex. E008, Jo Alene Dolan MDL deposition at 21-24. *See also* Ex. D0253, Brenot, F. et al., *Primary Pulmonary Hypertension and Fenfluramine Use*, Br Heart J. 1993 Dec;70(6):537-41.

disturbing findings. By mid 1995, Wyeth had also received numerous reports of heart valve disease in fenfluramine users, but deliberately chose not to investigate those cases, and did not follow up at all on those reports until the Mayo Clinic forced its hand in April 1997.[5] Even then, Wyeth intentionally deleted 17 of the 24 Mayo Clinic heart valve disease cases from its database and re-used the report numbers for other products, so that they would be untraceable by the FDA.[6] Moreover, Wyeth failed to perform studies of the effects of fen-phen and failed to perform post-market surveillance, as required by the FDA.

In late 1995 and early 1996, Wyeth was in the process of obtaining FDA approval for its new diet pill, Redux, which contained only dexfenfluramine, the potent half of fenfluramine. Wyeth did not want a "black box" warning about pulmonary hypertension or heart valve disease to be attached to the Redux package label, and Wyeth was determined not to generate bad information about Pondimin and fen-phen during the approval process, since Pondimin and Redux were essentially the same drug.[7]

Wyeth was successful in getting Redux approved and put on the market without the black box warning. Redux was approved by the FDA advisory committee by only one vote. One of the

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[4] Ex. B4810, Interneuron's summary of Servier's actions re 7/11 CPMP Hrg. Incl Private Mtg btw Servier & French FDAat AHP-Q-00139436.

[5] Ex. B0728; B0729; B0177 (three examples of separate adverse event reports received by Wyeth in March 1994); Ex. B4126 (adverse event reports ("AER") listing dated 6/5/96); Ex. B4598 (letter from Thompson to Sandage, 4/9/96); Ex. B0226 (2/24/97 contact report).

[6] Ex. B4805, Redux New Drug Application (3/12/97); Ex. B0144, AHP-X-00081780-86, FDA 483 report, AHP-W-00049956-63 (12/4/97); Ex. E014, Myers MDL deposition at 168-173; Ex. E013, MDL deposition at 131-135.

[7] A "black box" warning consists of prominently displayed text, surrounded by a black box, in a product's labeling. It is designed to draw the physician's attention to a serious side effect associated with the drug. Ex. E001, Acri MDL deposition at 122-124. Ex. E002, Ballard MDL deposition at 209-210. Ex. E012, Levine MDL deposition at 59-60. Ex. B4809, The survey revealed indicated that most physicians felt that the rate of risk of PPH determined in the IPPH study outweighed any benefits of the drug. Moreover, patients would not tolerate any such risk. Ex. B4102, Memo from Bunyaraksh to Distribution re: Redux forecast with and without black box warning, AHP-Q-00036824-5.

members who voted to approve, Dr. Illingworth, later testified that he would have voted against approval if he had been fully informed of the risks of the drug.[8]

As early as 1994 and 1995, Wyeth knew of far more reports of heart valve disease cases than it reported to the FDA.[9] However, Wyeth delayed warning physicians and patients about the risk of heart valve disease with its fenfluramines until July 1997, less than two months before Wyeth finally took these drugs off the market.[10] Most tragically, Wyeth did nothing to investigate the possible association of fenfluramine and heart valve disease for two years after it knew about these reports in 1995. Wyeth should have conducted an investigation in early 1995, and if it had, it would have found then what was discovered in August 1997, that a significant portion of long-term Pondimin users developed heart valve disease. Had that happened, Wyeth would never have completed its application for FDA approval of Redux, or at least Wyeth would have taken both Pondimin and Redux off the market before December 1996, when Ms. Buchanan was first prescribed Redux.

After the drugs were removed from the market as being unsafe or ineffective, the FDA banned both forms of fenfluramine as too dangerous for any patient anywhere. 21 CFR § 216.24.

ARGUMENT

I. PLAINTIFFS' PUNITIVE DAMAGES CLAIM IS NOT A FRAUD ON THE FDA CLAIM—*BUCKMAN* DOES NOT APPLY

Plaintiffs acknowledge that if they were making a tort claim based on a private cause of action that Wyeth had defrauded the FDA, *and thereby had caused harm to plaintiffs*, that such a claim clearly would be preempted by federal law pursuant to *Buckman*. However, plaintiffs

[8] Ex.E034, Illingworth dated 8/30/99 at 78.

[9] Ex. E016, Wilson MDL deposition at 109; Ex. E014, Myers MDL deposition at 161; Ex. E013, Moeller MDL deposition at 136-137.

[10] Ex. B0373, 7/24/97 `Dear Health-Care Provider` letter (Pondimin and Redux), AHP-W-00008049-50.

make no such claim. Plaintiffs' allegation that Wyeth is liable for punitive damages is not in itself a tort claim or a cause of action, for defrauding the FDA or anything else. The punitive damages are simply an element of damages in a products liability claim, the scope of which has been limited by the Ohio Legislature in cases against the manufacturers of drugs approved by the FDA. *Buckman* does not apply.

Ohio statute § 2307.80 was revised in 2004 by Senate Bill 80. The prior version controls this case, which allows plaintiffs to seek punitive damages in product liability cases pursuant to the following relevant provisions:

> (A) Subject to division (C) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection with a product liability claim unless the claimant establishes, by clear and convincing evidence, that harm for which the claimant is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product.
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> * * *
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> (C) If a claimant alleges in a product liability claim that a drug caused harm to the claimant, the manufacturer of the drug shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug that allegedly caused the harm was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the 'Federal Food, Drug, and Cosmetic Act,' 52 Stat. 1040 (1938), 21 U.S.C. 301-392, as amended, . . . unless it is established by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type. . . . *Former* Ohio Rev. Code § 2307.80.

To summarize, Ohio law allows punitive damages to be awarded in product liability cases if the plaintiff establishes by clear and convincing evidence that the manufacturer demonstrated flagrant disregard for the safety of the product's consumers. Subsection (C) of §2307.80,

however, does not allow punitive damages to be awarded in connection with a drug that was approved by the FDA unless the plaintiff proves by a preponderance of the evidence that the manufacturer fraudulently withheld information or misrepresented information to the FDA

The Ohio Legislature did not create a "punitive cause of action" or "punitive state tort claim" by providing an exception to the ban on punitive damages related to FDA-approved drugs. It merely added an evidentiary requirement for this type of damages. Allowing plaintiffs to avoid this ban on punitive damages by proving that Wyeth withheld information or provided false information to the FDA does not establish the kind of fraud on the FDA claim that is preempted by federal law per *Buckman*.

Wyeth argues that the court in *Bouchard v. American Home Products Corp*, 213 F.Supp.2d 802 (N.D. Ohio 2002), excluded all fraud on the FDA evidence. But, Wyeth misstates the court's ruling on this critical point. In fact, the *Bouchard* court held:

> Wyeth's motion will be granted. Having determined that private actions premised on fraud on the FDA are not permitted, the Court must decide to what extent, if any, evidence offered by Bouchard should be excluded. If, as Bouchard has stated, her claims are based on direct fraud against her and her healthcare provider, rather than the FDA, then her claims are not preempted, and *evidence concerning what information was an (sic) was not provided to the FDA might still be relevant*. *See* Globetti v. Sandoz Pharm. Corp., No. CV98-TMP-2649-S, 2001 WL 419160 (N.D.Ala. Mar.5, 2001) (Putnam, Chief Mag. J.); *Eve v. Sandoz Pharm. Corp.*, No. IP 98-1429-C-Y/S, 2002 WL 181972 (S.D.Ind. Jan.28, 2002). Evidence will be excluded outright when it is offered only to show that the FDA was misled, or that information was intentionally concealed from the FDA. Exclusion of further evidence may be necessary to prevent confusion of the jury as to the nature of Bouchard's claims; to the extent that is the case, further objections may be made at trial. 213 F.Supp.2d at 812 (*emphasis added*).

In this case, plaintiffs are not offering evidence of the information that Wyeth provided the FDA to support any fraud on the FDA claim, *nor any claim of fraud directly on them*, but only to establish entitlement to damages in connection with claims that clearly are not preempted by *Buckman*. The plaintiff in *Bouchard* was pursuing a fraud cause of action; plaintiffs here are not.

To avoid the punitive damages ban, Ohio law requires plaintiff to provide FDA-related evidence. *Former* Ohio Rev. Code § 2307.80(C). Plaintiffs should not be prevented from avoiding this ban on punitive damages by being prohibited from presenting the evidence required by Ohio statute. Plaintiff's claim for punitive damages stems from her product liability and negligence claims, which claims are not fraud on the FDA claims and are clearly allowed by *Buckman* and subsequent cases. As made clear by subsequent cases, *Buckman* did not ban all *evidence* related to information that was provided or not provided to the FDA. Furthermore, *Bouchard* clearly contemplated this when the court stated that such evidence might still be relevant. 213 F.Supp.2d at 812 (quoted above).

Accordingly, plaintiffs are entitled to allege and to attempt to prove punitive damages as allowed by Ohio law. Wyeth's motion should be denied.

II. IF OHIO STATUTE BANNING PUNITIVE DAMAGES IN FDA-APPROVED DRUG CASES IS INVALID UNDER *BUCKMAN*, THAT PROVISION MUST BE SEVERED FROM THE ACT

In the event the court decides that Ohio Rev. Code 2307.80(C) is unconstitutional in light of *Buckman*, the Court then must decide what effect that conclusion has on the effectiveness of the rest of Ohio Rev. Code 2307.80, which does not contain a severability provision. *Women's Med. Prof. Corp. v. Voinovich*, 130 F3d 187 (C.A.6th Ohio 1997); *State v. Hochhausler*, 668 NE2d 457 (Ohio S. Ct. 1996). Severability is a matter of state law. *Leavitt v. Jane L.*, 518 U.S. 137 (1996)(per curiam). Section 1.50 of Ohio's Revised Code provides that statutory provisions are presumptively severable:

> If any provisions of a section of the Revised Code or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the section or related sections which can be given effect without the invalid provision or application, and to this end the provisions are severable. Ohio Rev. Code § 1.50.

To sever a portion of a statute, the court must find that severing the provision will not fundamentally disrupt the statutory scheme of which the unconstitutional provision is a part. *State ex rel. Maurer v. Sheward*, 644 NE2d 369 (Ohio S.Ct. 1994). In *Maurer*, the court held

that Ohio courts must employ the following test to determine whether an unconstitutional provision may in fact be severed, and all three parts of the test must be met in order to sever the invalid provision:

> (1) Are the constitutional and the unconstitutional parts capable of separation so that each may read and may stand by itself?
>
> (2) Is the unconstitutional part so connected with the general scope of the whole as to make it impossible to give effect to the apparent intention of the Legislature if the clause or part is stricken out?
>
> (3) Is the insertion of words or terms necessary in order to separate the constitutional part from the unconstitutional part, and to give effect to the former only? *Maurer*, at 377 (quoting *Geiger v. Geiger*, 160 NE 28 (1927)).

So, the question is whether § 2307.80(C) can be severed from the rest of §2307.80. Under the test set forth by the Ohio Supreme Court, severing subsection (C) meets the test. First, subsection (C) stands alone in banning punitive damages in FDA-approved drug cases unless the manufacturer withheld or falsified information to the FDA, and subsection (C) can be severed without affecting the rest of § 2307.80. Second, subsection (C) is not so connected to the rest of that act that severing it affects the legislative intent of the rest of the act.

Wyeth, however, may argue that the court should sever in mid-sentence the last part of subsection (C), the exception to the ban on punitive damages when there is evidence of the manufacturer misconduct regarding providing FDA information. Wyeth may argue that the ban should stay but the exception should be removed. The Court should reject such an invitation. Such severing would certainly violate the Ohio Supreme Court's second test above, in that severing the provision mid-sentence would make it impossible to give effect to the apparent intention of the Legislature, which was to ban punitive damages except when the manufacturer lied to the FDA.

Compare *Garcia v. Wyeth-Ayerst Laboratories*, 385 F3d 961 (C.A. 6th Mich 2004). Michigan law immunizes FDA-approved drug manufacturers from all liability, with an exception for manufacturers who withhold from or misrepresent information to the FDA. The court severed

the "exception" provision as invalid under *Buckman*, leaving in place the provision that drug manufacturers are not liable.

Ohio's severability law differs from Michigan's and Ohio's drug manufacturers' product liability statutory scheme is structured very differently than Michigan's. Ohio's punitive damages statute cannot be similarly severed without violating Ohio law. *Women's Med. Prof. Corp. v. Voinovich*, 130 F3d 187 (C.A.6th Ohio 1997); *State v. Hochhausler*, 668 NE2d 457 (Ohio S. Ct. 1996).

Finally, under the third part of the test above, no insertion of words or terms is necessary to give meaning to the part not severed. If the Court finds that subsection (C) is unconstitutional under *Buckman*, the Court should sever the entire subsection (C). Furthermore, the Court should deny Wyeth's motion to dismiss plaintiffs' punitive damages claim.

CONCLUSION

Plaintiffs urge the Court to deny Wyeth's motion for partial summary judgment, asking the Court to bar plaintiffs from seeking punitive damages because Ohio law requires FDA-related evidence, allegedly contrary to *Buckman*. Plaintiffs' punitive damages claim is not a fraud on the FDA claim. *Buckman* does not apply.

However, should the Court determine that § 2307.80(C)--which bans punitive damages in FDA-approved drug cases--is unconstitutional under *Buckman*, that subsection must be severed from the act. Under either scenario, the Court should deny Wyeth's motion for partial summary judgment on punitive damages.

Dated: October 22, 2007.

Respectfully submitted:

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CERTIFICATE OF SERVICE

I hereby certify that on the 22nd of October, 2007, a copy of the foregoing **Plaintiff's Response to Wyeth's Motion for Partial Summary Judgment Relating to Punitive Damages** was filed electronically. Notice of this filing will be served by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Notices will be emailed and sent first class mail to the following:

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